

REMARKS

Claims 1 and 4-12 are pending. Claims 4 and 5 have been withdrawn from consideration. By this amendment, Applicant has amended Claims 1 and 12 and canceled Claims 8-10. Support for amendment of the Claims may be found in the specification and Claims as filed. No new matter has been added.

Applicant appreciates the time and consideration given to the undersigned by Examiner Ouspenski at the telephone interview held at the U.S. PTO on May 28, 2009. This paper is in furtherance of the discussions at the Interview.

I. WO 01/97842 is not prior art under 102(a)

In the office action mailed February 17, 2009 Claims 1, 7, and 10-12 were rejected under 35 U.S.C. § 102(a) over WO 01/97842 ("the WO '842 publication"). Example 39 of the '842 publication discloses C12 aqueous dilution of monoclonal antibodies to gamma interferon. Applicant maintains that under the law as set forth herein, the WO '842 publication is not proper prior art against presently pending claims.

The '842 publication was authored by Oleg Epstein, M. Shtark and T. Kolyadko. On May 11, 2009, Applicant submitted Declarations of Oleg Epstein, M. Shtark and T. Kolyadko showing un-rebutted evidence that Dr. Oleg Epstein was solely responsible for inventing the subject matter of the Example 39 of the '842 publication.

The named co-inventors of the present patent application as filed were Oleg Epstein, Evgeny Goldberg, and Alexander Dygay. Submitted herein are i) a Declaration of Oleg Epstein and ii) a Declaration of Alexander Dygay showing that Dr. Oleg Epstein was solely responsible for inventing the subject matter of the presently pending, namely potentiated antibodies to gamma interferon.

a. The Law Related To Scope of Prior Art

35 U.S.C. 102(a) provides that a person shall be entitled to a patent unless the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent. The term "others" in 35 U.S.C. 102(a) refers to any entity which is different from the inventive entity. See *In re Katz*, 687 F.2d 450, 215 USPQ 14 (CCPA 1982) (It is well established that for a reference to be available as prior art under 35 USC 102(a) that reference must be by another). The fact that an application has named a different inventive entity than the prior art, does not necessarily make that patent prior art. *Applied Materials Inc. v. Gemini Research Corp.*, 835 F.2d 279, 15 USPQ2d 1816 (Fed. Cir. 1988). When satisfactory evidence of inventorship in fact is provided, the court must look beyond the names of the inventors listed on the patents.

In *Riverwood International Corporation v. R.A. Jones & Co., Inc.*, 324 F.3d 1346 (CAFC 2003), the court examined the issue of whether different inventors listed on the cited art constituted the same inventive entity. In *Riverwood*, the prior art patent was to Ziegler, Olson and Lovold and the later patent at issue was to Ziegler, Lashyro and Vulgamore. The court (citing *In re DeBaun*, 687 F.2d 459, 462 (Cust. & Pat. App. 1982)) found that:

"What is significant is not merely the differences in the listed inventors, but whether the portions of the reference relied on as prior art, and the subject matter of the claims in question, represent the work of a common inventive entity. [emphasis added]."

In *In re Blout and Rogers*, 333 F.2d 928, 52 CCPA 751 (1964) a reference by Rogers alone, disclosing the invention of Blout-and-Rogers, was cited as prior art against the joint application of Blout-and-Rogers. Blout and Rogers filed an affidavit attributing the relevant disclosure of the Rogers patent to Blout-and-Rogers and thus showing that the invention was by Blout-and-Rogers and the prior art was by Blout and Rogers. Accordingly, the affidavit, showed that while the named "inventive entity" were not the same, the relevant part of the prior art were work of the same inventors named

in the Blout-and-Rogers application. The court held that the Rogers reference was not properly a reference against Blout-and-Rogers.

In *In re Mathews*, 408 F.2d 1393, 161 U.S.P.Q. 276, 56 CCPA 1033 (1969), the prior art was a patent by Dewey which disclosed but did not claim the invention claimed by Mathews. Mathews filed an affidavit showing that the relevant part of the disclosure of Dewey was his own work. Such showing made the prior art by Mathews and the invention by Mathews. Again, there was clear showing that the same author was the source of the subject matter at issue. The court stated that the "Dewey's affidavit and Mathews' oath accompanying his application are sufficient, we feel, to prove that the relevant disclosure in Dewey was a disclosure of Mathews' invention. The Dewey disclosure relied on, being a disclosure of Mathews' own invention, does not establish lack of novelty of Mathews' claimed invention." *In re Mathews*, 408 F.2d 1393, at 1396.

In *In re DeBaun*, 687 F.2d 459 (Cust. & Pat. App. 1982)) and *Avocent Huntsville Corp. v. ClearCube Technology, Inc.*, 443 F.Supp.2d 1284, (D.C. Ala 2006) the court examined the issue of what constitutes sufficient evidence in demonstrating inventorship. In *In re DeBaun*, the examiner rejected the claims of an application to DeBaun under 35 U.S.C. §103 in view of a patent to DeBaun-and-Noll. DeBaun argued that the art cited against him (the patent to DeBaun-and-Noll) was not prior art under § 102(e) and submitted a declaration stating that he was the sole inventor of the subject matter on which the examiner's rejection relied. The Examiner maintained the rejection and concluded that the declaration was insufficient to show that DeBaun was the sole inventor. The Board sustained the rejection. The court in *DeBaun*, stated that when one of two (or more) inventors named on a patent contends that certain elements of the patent claims are his own work, he must provide satisfactory evidence showing that the reference is his own work, 687 F.2d at 463 (citing *In re Facius*, 56 CCPA 1348, 408 F.2d 1397, 1406 (Cust. & Pat. App. 1969). See also *In re Land* (an unequivocal declaration suffices, provided it is corroborated.). The court found the unequivocal declaration to be satisfactory and sufficient evidence, and in reversing the rejection, the court held that the examiner should have considered the declaration as evidence that

DeBaun was the sole inventor. *Id.* at 462.

In *Avocent Huntsville Corp. v. ClearCube Technology, Inc.*, *supra*, defendants contended that a patent issued to Asprey as the sole inventor (the sole patent) constitutes §103 prior art as to claims 1, 6 and 16-18 of the patent issued to Asprey, Kirshtein and Lusk (the joint patent). The questions was whether the inventive entities were the same or different. Avocent submitted the sworn declarations of Asprey and Kirshtein, two of the three inventors named in the joint patent declaring that Asprey was the sole inventor of the subject matter recited in claims 1, 6 and 16-18 of the joint patent. The court stated that Asprey's statements were wholly corroborated by Kirshtein's declaration who swore that he did not invent the subject matter recited in claims 1, 6 and 16-18 of the joint patent and that to his knowledge Asprey was the sole inventor of said claims.

**b. The Law Establishes That WO '842 Is Not Prior Art Under §102(a)**

In the present case, Applicant submitted Affidavits demonstrating that Dr. Oleg Epstein was solely responsible for inventing the subject matter of Example 39 of the '842 publication. Herewith submitted is the Affidavit of Dr. Oleg Epstein which states that he is the sole inventor of the subject matter of claims 1, 4-5 and 11-12 of the present application. His statement is corroborated by the Affidavit of Alexander Dygay. Thus, Applicant has provided satisfactory and unequivocal evidence showing that the subject matter of the claims and the portion of the referenced relied on as prior art is his own work. See *In re Katz*, 687 F.2d 450, 215 USPQ 14 (CCPA 1982); *Riverwood International Corporation v. R.A. Jones & Co., Inc.*, 324 F.3d 1346 (CAFC 2003); *In re Blout and Rogers*, 333 F.2d 928, 52 CCPA 751 (1964); *In re Mathews*, 408 F.2d 1393, 161 U.S.P.Q. 276, 56 CCPA 1033 (1969); *In re DeBaun*, 687 F.2d 459 (Cust. & Pat. App. 1982); and *Avocent Huntsville Corp. v. ClearCube Technology, Inc.*, 443 F.Supp.2d 1284 (D.C. Ala 2006);

Applicant, therefore, submits that the WO '842 publication is not available as a §102(a) reference against the presently pending claims of the present application and is thus, not an appropriate reference under section §102(a). Accordingly, the WO'842 publication should be removed as a prior art reference and the Applicant submits that claims 1, 4-5 and 11-12 are in allowable form.

## II. Inventive Entity

Based on the foregoing, it is evident that Dr. Oleg Epstein is the sole inventor of claims 1, 6-7 and 11-12 as now pending. Under 37 CFR §1.48(b) when claims are narrowed or changed so that former inventors are no longer properly named, the attorney must request correction of inventorship to reflect amendment of the claims. Since, neither Goldberg nor Dygay are in fact co-inventors of claims 1, 6-7 and 11-12, Applicant submits that correction of inventorship is required under 37 CFR §1.48(b), so as to delete Alexander Mikhailovich Dygay and Evgeny D. Goldberg as inventors and identify Dr. Oleg I. Epstein as the sole inventor of claims 1, 6-7 and 11-12.

While Applicant does not represent that Goldberg and Dygay were properly or improperly named in the application as filed, Applicant asserts that the inventive efforts of each inventor being deleted are clearly no longer claimed in the present nonprovisional application. Applicant further requests that the Examiner forward the application to the Office of Initial Patent Examination for issuance of a corrected filing receipt and correction of Office records to reflect the inventorship as corrected.

In view of the foregoing, the Applicants submit that all claims are in condition for allowance and respectfully requests withdrawal of the anticipation rejection. Accordingly, both reconsideration of this application and its swift passage to issuance are earnestly solicited. In the event that there are any fees due and owing in connection with this matter, please charge the same to our Deposit Account No. 50-4711.

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